

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
**(Under 37 CFR 1.97(b) or 1.97(c))**

Docket No.  
Army156A

In Re Application Of: Eckels et al.

Serial No.	Filing Date	Examiner	Group Art Unit
not known	July 24, 2003	not known	not known

Title: Live-Attenuated Multivalent Dengue Vaccine

**(DIVISIONAL APPLICATION OF SERIAL NO. 09/535,117)**

Address to:  
**Commissioner for Patents**  
P.O. Box 1450  
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1.  The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2.  The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

the statement specified in 37 CFR 1.97(e);

**OR**

the fee set forth in 37 CFR 1.17(p).

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**Live-Attenuated Multivalent Dengue Vaccine**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- A check in the amount of \_\_\_\_\_ is attached.
- The Director is hereby authorized to charge and credit Deposit Account No. \_\_\_\_\_  
as described below.
  - Charge the amount of \_\_\_\_\_
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*Marlana Titus*  
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Typed or Printed Name of Person Mailing Certificate

\*This certificate may only be used if paying by deposit account.

*Marlana Titus*  
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Signature

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CC:

Dated: July 24, 2003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of  
Eckels et al.

Group Art Unit: not known

Serial No: not known  
Divisional app. of Serial No.: 09/535,117

Examiner: not known

Filed: July 24, 2003

FOR: Live-Attenuated Multivalent Dengue Vaccine

\* \* \* \* \*

July 24, 2003

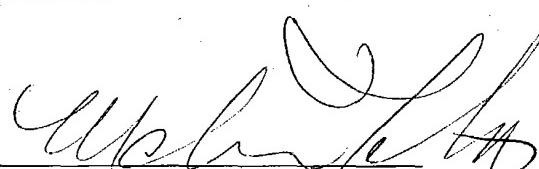
**STATEMENT PURSUANT TO 37 CFR 1.198(d)**

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

In connection with the above-identified divisional application, Applicants have filed concurrently herewith an Information Disclosure Statement and corresponding PTO-1449 form citing a number of references. Copies of all the references cited on the PTO-1449 form were submitted and considered in parent application Serial No. 09/535,117 (filed 3-24-00). Pursuant to 37 CFR 1.198(d), copies of these references are not required to be supplied in this divisional application.

By: \_\_\_\_\_

  
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Applicant(s) Eckels et al.	
		Filing Date July 24, 2003	Group Art Unit not known
*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
C	Halstead et al., 1984, "Selection of attenuated Dengue 4 viruses by serial passage in primary kidney cells," Am J. Trop. Med. Hyg., 33(4), pp. 654-665.		
D	Halstead et al., 1984, "Selection of attenuated Dengue 4 viruses by serial passage in primary kidney cells," Am J. Trop. Med. Hyg., 33(4), pp. 666-671.		
E	Halstead et al., 1984, "Selection of attenuated Dengue 4 viruses by serial passage in primary kidney cells," Am J. Trop. Med. Hyg., 33(4), pp. 672-678.		
F	Halstead et al., 1984, "Selection of attenuated Dengue 4 viruses by serial passage in primary kidney cells," Am J. Trop. Med. Hyg., 33(4), pp. 679-683.		
G	Hayflick, 1988, "History of cell substrates used for human biologicals", Symposium on Continuous Cell Lines as Substrates for Biologicals, Arlington, Virginia, USA, pp. 11-26.		
H	Hoke et al., 1990, "Preparation of an attenuated Dengue 4 virus vaccine", Am J. Top. Med. Hyg., 43(2), pp. 219-226.		
I	Marchette, 1990, "Preparation of an attenuated Dengue 4 virus vaccine", Am J. Top. Med. Hyg., 43(2), pp. 212-218.		
K	Mizrahi, ed., Viral Vaccines, "WHO Attitude to Viral Vaccines", Wiley-Liss, New York (1990), pp. 39-60.		
L	Putnak et al., 1996, "Development of a purified, inactivated, Dengue-2 virus vaccine prototype in vero cells: immunogenicity and protection in mice nad Rhesus monkeys," J. Infectious Dis., 174, pp. 1176-84.		
M	Russell, et al., "A plaque reduction test for dengue virus neutralizing antibodies", J. Immunology, Vol. 99, No. 2, 1967, pp.285-290.		
N	Scott, 1983, "Dengue 2 vaccine: Dose response in volunteers in relation to yellow fever immune status," J. Infectious Diseases, Vol. 148, No. 6, pp.1055-1060.		
O	Sukhayachana et al, 1966, "Tissue culture techniques for the study of dengue viruses", Abrege des Communications, Bull. WHO 35, pp. 65-66.		
MINER		DATE CONSIDERED	
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P	Zoller and Smith, 1984, Laboratory Methods, "Oligonucleotide-directed mutagenesis: a simple method using two oligonucleotide primers and a single-stranded DNA template", DNA, Vol. 3, No. 6, pp.479-488.		
Q	Bhamarapravati, 1987, "Immunization with a live attenuated dengue-2-virus candidate vaccine: clinical, immunological and biological responses in adult volunteers", Bull. WHO, 65(2), pp.189-195.		
R	Conrad et al., "Infection with Nippostrongylus Brasiliensis or injection of anti-IgD antibodies markedly enhances Fc-receptor-mediated interleukin 4 production by non-B, non-T cells", J. Exp. Med., Vol. 171, pp.1497-1508.		
S	Dharakul, et al., "Dengue virus-specific memory T cell responses in human volunteers receiving a live attenuated dengue virus Type 2 candidate vaccine", J. Infect. Dis., Vol. 170, pp. 27-33.		
T	Edelman et al., "A live attenuated Dengue-1 vaccine candidate passaged in primary dog kidney cell culture is attenuated and immunogenic for humans", 1994, Am. J. Trop. Med. Hyg., 170, pp. 1448-1455.		
U	Halstead, 1978, "Studies on the attenuation of Dengue 4", Asian J. Infectious Dis., Vol. 2, pp. 112-117.		
V	Halstead, 1970, "Long 'cure' improves results of pig heterograft heart valves," JAMA, Vol. 211, No. 6, pp. 911-916.		
W	Johnson and Roehrig, "New mouse model for Dengue virus vaccine testing", J. Virology, Jan. 1999, Vol. 73, No. 1, pp. 783-786.		
X	Kontny et al., "Gamma interferon augments Fc receptor-mediated Dengue virus infection of human monocytic cells", J. Virology, Nov. 1988, Vol. 62, No. 11, pp. 3928-3933.		
Y	Kurane et al., "Dengue virus-specific human T cell clones", J. Exp. Med., Vol. 170, 1989, pp. 763-775.		
Z	Kurane et al., "Activation of T lymphocytes in dengue virus infections", J. Clin. Invest., Vol. 88, 1991, pp. 1473-1480.		
AA	Kurane et al., "T cell activation in vivo by Dengue virus infection", J. Clin. Lab. Immunol., 1995, vol. 46, pp.35-40.		
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BB	Peters, "Actions of cytokines on the immune response and viral interactions: an overview", Hepatology, Vol. 23, 1996, pp. 909-916.		
CC	Sittisombut et al., "Lack of augmenting effect of interferon- $\gamma$ on Dengue virus multiplication in human peripheral blood monocytes", J. Medical Virology 45:43-49, 1995.		
DD	Sabin, 1959, "Dengue", Viral and Rickettsial Infections of Man, Philadelphia: JB Lippincott Company, pp. 361-373.		
EE	Simmons et al., "Experimental Studies of Dengue", 1931, Manila Bureau of Printing, pp. 1-489.		
FF	Wisseman and Sweet, "Immunological studies with Group B arthropod-borne viruses", Am J. Trop. Med. Hyg., Vol. 11, pp. 570-575 (1962).		
GG	Yuill et al., "Dengue-virus recovery by direct and delayed plaques in LLC-MK2 cells", Am. J. Trop. Med. Hyg., Vol 17, 1968, pp. 441-448.		
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### **Group Art Unit**

not known

## **U.S. PATENT DOCUMENTS**

**FOREIGN PATENT DOCUMENTS**

**OTHER DOCUMENTS** (*Including Author, Title, Date, Pertinent Pages, Etc.*)

	A	Edelman, et al., "A Live Attenuated Dengue-1 Vaccine Candidate (45AZ5) Passaged in Primary Dog Kidney Cell Culture SIs Attenuated and Immunogenic for Humans", J. Infectious Diseases, 1994;129:1448-1455 (December).	
	B	Angsubharkorn et al., "Dengue-3 (16562) PGMK 33 Vaccine: Neurovirulence, Viremia and Immune Responses in Macaca Fascicularis", Southeast Asian J. Trop. Med. Public Health, Vol. 25, No. 3, September 1994.	

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C (XP-002150293) Sun et al., Program Abstracts from the First Annual Conference on Vaccine Research, May 30-June 1, 1998, "Phase I Study of Two Doses of Monovalent Live-Attenuated Dengue Virus Vaccines" (2 pages).

D Vaughn, et al., "Testing of a dengue 2 live-attenuated vaccine (strain 16681/PDK 53) in ten American volunteers", Vaccine, Vol. 14, No. 4, pp. 329-336, 1996.

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Hoke et al., "Preparation of an attenuated Dengue 4 virus vaccine II safety and immunoactivity in humans", American J. of Tropical Medicine &amp; Hygiene, Lawrence, KS, US, Vol. 43, No. 2, August 1990, pages 219-226.

E

D. J. Gubler, "The global pandemic of dengue/dengue haemorrhagic fever: Current status and prospects for the future", Annals Academy of Medicine Singapore, vol. 27, no. 2, March 1998, pages 227-234.

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Putnak et al., "Development of a purified, inactivated, dengue-2 virus vaccine prototype in vero cells: immunogenicity and protection in mice and rhesus monkeys", J. of Infectious Diseases, vol. 174, no. 6, 1996, pages 1176-1184.

G

Puri Beena et al., "Molecular analysis of dengue virus attenuation after serial passage in primary dog kidney cells", J. of General Virology, vol. 78, no. 9, 1997, pages 2287-2291.

H

Marchette et al., "Preparation of an attenuated dengue 4 virus vaccine I pre-clinical studies", American J. of Tropical medicine &amp; Hygiene, Lawrence, KS, US, vol. 43, no. 2, August 1990, pages 212-218.

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Bhamarapravati et al., "Live attenuated tetravalent dengue vaccine", Vaccine, GB Butterworth Scientific Guildford, vol. 18, March 2000, pages 44-47.

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